UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968
Case No.: 2:08-md-1968

THIS DOCUMENT RELATES TOALL CASES AND SPECIFICALLY:
Case No. 2:09-cv-0671
Case No. 2:09-cv-0768

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL LIABILITY EXPERTS

I. INTRODUCTION

Plaintiffs in the matter of *Kathy McCornack, et al. v. Actavis, et al*., Case No. 2:09-cv-0671, ("*McCornack* Plaintiffs") and *Scottie Vega, individually and as next friend of Christopher Vega, a minor and surviving nature child of Mimi Rivera-Vega v. Actavis, et al*, Case No. 2:09-cv-0768 ("*Vega* Plaintiff") , hereby respectfully submit the following:

II. STATEMENT OF FACTS

A. Actavis' Discovery of Double-Thick Digitek: On November 30, 2007, packaging of 0.125 mg Digitek batch no.70924A1 was halted after a worker found two double-thick tablets in the hopper (bucket nos. 15 and 16). Pl. Ex. 44; Pl. Ex. 16, (Bates 2, 4); Pl. Ex. 500, (Bates 678, ¶39, A31-32). Half of the 4.7 million tablet batch (bucket nos. 1-14) had already been packaged for distribution. The ensuing FDA investigation led to a recall of all Digitek (and certain other Actavis' products), and ultimately the recall of all products produced at the Little Falls facility. *See, II.D, below*.

Visual inspection of the two buckets in the hopper (nos. 15-16) and the two subsequent buckets (nos. 17 and 18) was conducted, finding a third defective double-thick tablet in bucket 17. The remainder of the unpackaged portion of the batch (bucket nos. 19-34) was visually "inspected" by keeping a "watchful eye" ***as the tablets traveled down the bottle filler channels***.[1] Pl. Ex. 44, Pl. Ex. 16, (Bates 4); Pl. Ex. 500, (Bates 678, ¶39 and A31-32). A fourth and fifth defective double-thick tablet were found in bucket no. 34. Pl. Ex. 16, (Bates 4).

Later, the 4,772 packaged 1,000 tablet bottles comprising the batch were emptied onto a table-top, and visually "inspected." Actavis discovered 15 more double-thick tablets. Pl. Ex. 16, (Bates 55-56, 61). Finally, Actavis visually inspected 1,330 tablets (40 tablets from each full bucket, 10 from the partially-filled bucket). Pl. Ex. 16, (Bates 61-63). In total, 20 defective, double-thick tablets were found, scattered randomly throughout the 4.7 million tablet batch.

At all stages, this "inspection" was limited to a naked-eye, visual scanning of the tablets. *See citations supra*. The defects at issue, however, offer minimal or no visual cues to ensure the efficacy of such a cursory visual inspection. Defendants themselves argue that a double-thick tablet cannot reliably be detected by eye. *Doc. No. 527*, p. 1, ("Thickness of a tablet only millimeters in size is a measurement. It is not something that can be 'eyeballed.'").[2] Related excess-weight and blending defects (*see, II.B, below*) would have no visual cues whatsoever.

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[1] A single batch of Digitek, comprising approximately 4.8 million pills, is typically manufactured and packaged in just a few days. Even assuming 24-hour per day packaging, this would still be more than one thousand pills per minute traveling down the bottle filler channels.

[2] Curiously, defendants also take the exact opposite position when advantageous. On one hand, as quoted above, defendants argue that a double-thickness tablet cannot be "eyeballed" (attacking the reliability of a nursing home's report of finding a defective double-thickness pill). Conversely, defendants argue that "this defect [double-thickness tablets] is easy to visibly identify" (defending Actavis' cursory visual inspection protocol *supra*). *Compare*, Doc. No. 527, p. 1 and Def. Ex. 29 (Doc. No. 522-29, p., 7).

Actavis admitted that it could not confirm any cause for these defective double-thick tablets, speculating that it might have resulted from a mid-batch stop and re-start of one (of two) tablet press. Pl. Ex. 16, (Bates 6). Other records, however, suggest that the tablet press itself may have been defective. Pl. Ex 97; Pl. Ex. 227.[3] Either way, Actavis chose to treat this as an "isolated incident", concluded no other batches were impacted, and quickly released the repackaged batch for distribution. Pl. Ex.16, (Bates 5-7).

B. Actavis' History of Related Production Deficiencies: Actavis (and its predecessor, Amide, with the same facilities and management from 1989-2008), has a decades-long history of serious production deficiencies. The FDA has issued Actavis no less than 26 Form 483's (most documenting numerous quality control deficiencies) and 6 warning letters highlighting "significant deviations" from Current Good Manufacturing Practice ("cGMP") regulations (21 *C.F.R.* Parts 210 and 211). Pl. Ex. 500, *generally*. Between 1990 and 2008, Actavis' products were the subject of four separate recalls, three related to incorrect tablet thickness, weight, or blending, (*i.e.*, excess or insufficient dosage). The last of these recalled every single Actavis product produced at its Little Falls facility. Pl. Ex. 500, *and II.D, below*. For much of this time, (from 1992-2002, and 2008 forward), Actavis has operated under the terms of a consent decree because the company was deemed incapable of safely operating its facilities without third-party oversight. Pl. Ex. 500, (A3, A47, B45).

The full history of Actavis' documented failure to ensure that products were produced within specifications is succinctly summarized in Dr. David M. Bliesner's expert report (Pl. Ex. 500, with repeated instances of incorrect tablet thickness, weight, and/or blending, including product packaged for shipment or found in the marketplace. *Inter alia*:

[3] Replacing the Digitek tablet presses has actually been a longstanding topic of discussion at Actavis. *See also, e.g.*, Pl. Ex. 258, Pl. Ex. 259.

- In December 1990, Actavis initiates a Class II recall for variation in tablet size resulting in sub- and super-potent product. Pl. Ex. M45; Pl. Ex. 500, (B5, A33).

- In March 1994, the FDA documents loss of active ingredient during drying and final blending/compression without concern or explanation by Actavis. Pl. Ex. 500, (A4).

- In October-November 2001, the FDA finds "thin" (*i.e.*, sub-strength) tablets, rejecting more than 1,600 tablets during a visual inspection, and no assurance that all defective tablets had been found. Pl. Ex. 236; Pl. Ex. 500, (A11).

- On June 8, 2004, a double-thick/double-weight 0.25 mg digoxin tablet from a batch produced seven months prior (November 2003) with tablet presses #67 and 71 is found by a pharmacist. Pl. Exs. 241, 242, 128; Pl. Ex. 500, (A13-A15).

- In July-August 2006, the FDA concludes that Actavis has failed to document all laboratory and manufacturing deviations. Pl. Ex. 90; Pl. Ex. 500, (A18).

- In the first half of 2007, 19 product batches have blend uniformity failures, including two batches of digoxin. One of these two is released. Pl. Ex. 183.

- On April 3, 2007, Actavis confirms 17 Adverse Drug Events (including elevated digoxin blood levels and an "unknown" potency question) and blend uniformity defects (particularly with respect to batch no. 60319A) relating to the 184 million 0.25 mg digoxin tablets produced in 2006 (44 batches). Pl. Ex. 253; Pl. Ex. 500, (A27).

- On May 22, 2007, Actavis reports out-of-specification digoxin tablets (weight) in batch no. 5453A (produced in 2005). Pl. Ex. 500, (A26); Pl. Ex. 501.

- On November 30, 2007, 20 defective double-thick 0.125 mg digoxin tablets are fortuitously discovered during packaging, scattered throughout digoxin batch no. 70924A1, produced with tablet presses #67 and 71. Following a cursory visual inspection, the product is released to market anyways. Pl. Exs. 44, 16; Pl. Ex. 500, (A31-32), *and see, II.A, supra*.

- In late 2007, Actavis speculates a blend failure with respect to digoxin batch nos. 70148A and 70207A could have had various causes, including dry (low humidity) winter conditions during winter and API particle size variations. Pl. Ex. 159; Pl. Ex. 500, (A34).

- In January 2008, Mylan (a Digitek distributor), confirms two batches of 0.125 mg Digitek with out-of-specification assays (too low). Pl. Ex. M14; Pl. Ex. 500, (A52).

- On February 20, 2008, Actavis' discovers sub-thickness 0.25 mg Digitek tablets in bucket no. 2 of batch no. 80133A. Pl. Ex. 217, (Bates 515); Pl. Ex. 500, (A54).

- In March 2008, UDL, another Digitek distributor, notes the complaint of a consumer who received sub-thickness tablets. Pl. Ex. M69; Pl. Ex. 500, (A36).

- On April 1, 2008, packaged overweight 0.125 mg Digitek is discovered near the end of packaging batch no. 80228A1, (bucket nos. 26 and 27). In one 5,000 pill bottle, 17 out of 30 pills inspected are of excess weight, and 17 out of 50 tablets are in excess of 120 mg, (10-20% above weight specifications). Pl. Ex. 141; Pl. Ex. 500, (A39); Pl. Ex. 16, (Bates 4).

- From March-May 2008, the FDA inspects Actavis due to the "significant cGMP deficiencies" relating to double-thick tablets and blend failures, ultimately prompting the Digitek recall. *See, II.C-D, below*.

- On April 24, 2008, all Digitek is recalled due to double-thickness, overweight, excess-strength tablets. Certain other Actavis products are also recalled and production of all drugs is suspended. *See, II.C-D, below*; Pl. Ex. 113; Pl. Ex. 500, (A35); Pl. Ex. 502, (Bates 782-83).

- In late April 2008, just days after the recall, a Digitek tablet "obviously of double thickness" is discovered at a Massachusetts nursing facility. Doc. No. 527-1, (Page ID# 12224); Pl. Ex. 621.

- In August 2008, Actavis recalls all 66 products manufactured at its Little Falls facility. Pl. Ex. 500, (B43).

- Actavis' rejects 8 of 19 batches of 0.125 mg Digitek produced in early 2008 (after the November 2007 incident) in connection with the recall, including one with tablets out-of-specification for weight. Pl. Ex. 144, (Bates 357-358 and n. 4); Pl. Ex. 500, (A48).

- In January 2009, Actavis reports nine complaints (from Aug.2008- Jan. 2009) of double-thick Digitek found in the marketplace. Pl. Ex. 73.

Dr. Bliesner, a respected expert concerning Current Good Manufacturing Practice ("CGMP") and Quality Safety Regulations compliance for the pharmaceutical industry, reviewed the foregoing history (and numerous other similar reports). He concludes that Actavis (and its predecessor) have a documented, 27-year failure to comply with cGMP's. He further concludes that the systemic failure to implement quality control systems and to comply with applicable safety regulations resulted in adulterated Digitek with double-thick/double-weight/excess strength reaching the marketplace. Pl. Ex. 500, (Bates 683); Pl. Ex. 620. His conclusions are echoed by no less than three other respected pharmaceutical industry and compliance experts. *See, e.g.*, Pl. Ex. 511; Pl. Ex. 514; Pl. Ex. 513, (450:25-454:6, 411:9-24); Pl. Ex. 516.

C. The FDA's March - May 2008 Investigation: From March –May 2008, the FDA inspected Actavis' Riverview, New Jersey facilities (the new site for the former Little Falls facility's operations). The FDA succinctly describes its longstanding concerns:

> … significant cGMP deficiencies including but not limited to out of specification in-process, finished product and stability results for more than [redacted] prescription pharmaceutical products; release of Digoxin 0.125 mg lot #70924A2 following visual inspection of the [redacted] to remove "double thick tablets"; failure of the Quality Unit to reject products not meeting specifications, to complete Quality Assurance investigations, to expand investigations to other lots and products … and to respond to out of specification products on the marketplace. Analytical methods requiring remediation remained in use … . Written procedures were not followed and changes with potential product quality impact were not reviewed or approved by the Quality Unit. No market action was taken by the Quality Unit for any products on the market at the [March 18, 2008] initiation of the inspection despite the confirmed out of specification in-process, finished product, and stability results.

Pl. Ex. 91, (Bates 227); Pl. Ex. 500, (A37).

The FDA excoriates Actavis' inadequate quality control procedures, failure to follow those procedures, failure to reject out-of-specification product, failure to adequately review product to ensure it is within specification (whether or not it has been distributed), failure to investigate out-of-specification product in other production batches and products produced under the same systems and facilities, and failure to fully document investigation of out-of-specification product. Pl. Ex. 91, *generally*; Pl. Ex. 500, (A37).

The FDA concludes that but for a recall there simply could be no assurance of the strength, quality and purity of Actavis' products:

> Commitments to recall finished products from the marketplace were initiated on 4/9/08 and continued throughout the inspection for such products as Digoxin Tablets … . However, there is no assurance of the strength, quality and purity of the approximately [redacted] of other products that remain on the market, all lots remaining in the two distribution centers, and the in-process products … .

Pl. Ex. 91, (Bates 227); Pl. Ex. 500, (A37).

D. Digitek Recall: A little over a month after the start of the FDA inspection, Actavis finally acted upon its prior commitment to recall its defective products. Pl. Ex. 91, (Bates 227); Pl. Ex. 500, (A37). On April 24-25, 2008, Actavis instituted a nationwide recall of all Digitek.

Initially, Actavis had intended to recall only the single batch of defective 0.125 mg Digitek which had been released in January 2008 despite the November 2007 discovery of double-thick tablets. Pl. Ex. 503, (139: 12-19, 131-139) *and see, II.A, supra*. But under pressure from the FDA (Pl. Ex. 91, *and see supra*), Actavis' CEO Robert Wessman expanded the recall to all Digitek within its expiration date, from any batch and any tablet size, from all distributors, retailers, ***and*** consumers. At the same time, Actavis committed to recall several other products too. Pl. Ex. 113; Pl. Ex. 91, (Bates 227); Pl. Ex. 500, (A37); Pl. Ex. 504-506; Pl. Ex. 503, (139:12-19, 131-139). By late May, Actavis had ceased production and shipment of the remainder of its products. Pl. Ex. 502. By August, Actavis had recalled all 66 products manufactured at its Little Falls facility. Pl. Ex. 500, (A63), *and see*, www.fda.gov.

The expanded Digitek recall alone involved two full years of production (March 2006 - April 2008), 152 batches, and several hundred million tablets. Pl. Ex. 113. (Just one recall credit issued to CVS/Caremark exceeded $2.25 million. Pl. Ex. 504, (p. 4.) Actavis has been circumspect about the full cost of the Digitek recall. Pl. Ex. 500, (A50).

One iteration of the recall notice, sent by Actavis to its "Valued Customers", provided:

> This recall notice has been initiated due to overweight tablets. Depending on the constituency of the tablets, double the dose size is taken, it can be expected that digitalis toxicity can occur in individuals taking daily doses or in patients with renal insufficiency. Toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can result from excessive digitalis intake. If increased thickness is due to clinically inert substances, then a decreased amount of digitalis may be observed, leading to exacerbation of the underlying cardiac disease (congestive heart failure and arrhythmia) due to lack of therapeutic efficacy.

Pl. Ex. 113; Pl. Ex. 505, (Bates 1218); Pl. Ex. 120; Pl. Ex. 500, (A35, A57). Actavis' health hazard evaluation, the basis (nearly verbatim) for this notice, concluded that a double-dose ***of 0.125 mg Digitek*** would be expected to cause digoxin toxicity for daily-dose patients. Pl. Ex. 220.[4]

Another iteration of the recall notice issued by Digitek's distributors (quoting Actavis' April 25, 2008 press release) provided:

> The voluntary recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.
>
> Digitek is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake.

Pl. Ex. 504, (Bates 1195, 1198-99, 1215-16).

The consumer-level recall notice mailed to pharmacy retailers dated May 2, 2008, less than two months after his death, similarly advised:

> On April 25, 2008, Actavis Totowa LLC, the manufacturer of Digitek 0.125 mg and Digitek 0.25 mg tablets, issued a Patient Level Recall of all lots of these products as a precaution **because the tablets may be double the appropriate thickness and could contain twice the approved level of active ingredient**. Because of this, the manufacturer is recalling all lots of these products.

Pl. Ex. 506, (Bates 1222, *emphasis in original*).

II. ARGUMENT

A. Plaintiffs Didn't Find What Actives Never Looked For.

The Defendants make the disingenuous argument that individual plaintiffs should be able to find another defective pill, other than the one they ingested already that made them sick. In

[4] The evaluation did not specifically address the expected health hazards from taking a double-dose of 0.25 mg Digitek. Pl. Ex. 220.

Batch 70924A1, Defendants contend that all defective pills were found and that was only to 20 pills out of more than 4.7 million. Given that each plaintiff had a maximum of perhaps 30-100 pills at any time, the odds of locating a second defective pill (apart from the one ingested) are not a needle in a haystack, they are a needle in a 10,000 acre hayfield. Defendants admit that there is a lack of physical cues that would alert a consumer that a tablet was too big.

Defendants ignore the several reports of non-spec tablets in the marketplace; ignore the significance that at least 15 tablets were packed for distribution and would not have been discovered, had Defendants not fortuitously found 2 tablets half-way through a 4.7 million tablet production run.

More telling is the fact that after 159 batches of Digitek were recalled, estimated to be over 500 million tablets(PLF Exh. 113), the Defendants never examined the recalled product to determine if they were right about the magnitude of their manufacturing error. This ostrich approach to product safety is evidence of what they really believed about the likelihood of product reaching the consuming public. If they really believed that the 20 tablets found were the only out of specification tablets they made, it would not have been too burdensome to confirm that with at the very least a sampling of the recalled product. They did not and the experts and jury are entitled to consider this fact in judging the probability that other out of specification tablets made their way to the market place.

B. Plaintiffs' Quality Control Experts Methodology is Sound

1. Dr. David Bliesner

Dr. David Bliesner is a Ph.D chemist who consults with the pharmaceutical industry. Dr. Bliesner has prepared a declaration responding to the unfounded criticisms of his opinions and their basis. (Pl. Ex. 500, Bliesner Declaration Pl. Ex 620) In general, the Defendants set up the

classic straw man argument in their criticism of Dr. Bliesner. They impose upon Dr. Bliesner (and all of Plaintiffs' defect experts), an inapplicable standard and then criticize these professionals for not meeting that standard. In the case of Dr. Bliesner, Defendants questioned him extensively regarding projects he has done for his pharmaceutical clients. The projects Dr. Bliesner did for his private clients, that the Defendants questioned him about in his deposition, are different than the analysis he did in this case. (Pl. Ex.500, Bliesner Declaration Pl.Ex. 620) As explained in Dr. Bliesner's declaration, he performed an analysis of the "Quality Systems" at the Defendants' manufacturing facilities. *Id.* Quality Systems is a component of the product delivery system of any pharmaceutical company. *Id.* The integrity and actual performance of a company's Quality Systems is the measure of how well a company will be able to adhere to good manufacturing practices. *Id.* The actual performance of a company's Quality Systems tell us whether they have the appropriate processes and personnel in place to detect defective products and prevent them from reaching the consuming public. *Id.* Dr. Bliesner did not do and could not have done a full systems audit of the Defendant's manufacturing facility. *Id.* To do that type of consulting project, necessitates the full cooperation of the client, unfettered by the limitations and limited scope of legal discovery. *Id.* Dr. Bliesner performed an analysis of the quality and integrity of the Quality Systems, also known as Quality Assurance, program of the Defendant. *Id.* As explained by Dr. Bliesner, the Quality Systems program is the last line of defense that protects the consuming public from being exposed to defective products in the market place. *Id.* This type of analysis is customary in the industry. *Id.* This is the type of work that Dr. Bliesner does for his clients. *Id.* He is qualified to make this judgment. *Id.* It is the most relevant analysis in answering the question: Did defective Digitek tablets make it past the Defendants' manufacturing and inspection personnel and into the market place? *Id.*

Dr. Bliesner did an extensive analysis of the performance of the Defendant's Quality Systems. (Pl. Ex.500, Bliesner Report and Bliesner Declaration Pl. Ex. 620) The documentation he reviewed is set out in detail in his report. *Id.* Both the facts and the documents supporting the facts set out above were all part of Dr. Bliesner's data base and analysis. *Id.* The measure of the performance of a company's Quality Systems is found in what they do when something goes wrong. *Id.* Good Manufacturing Practices (GMP) is designed to consistently produce products within specification. The GMPs are validated and approved by the FDA. This case is not about whether or not the Defendants followed proper manufacturing processes. It is a given that they did not. They admit that the manufacturing process failed. That failure resulted in a massive recall of product. The question in this case is whether after the manufacturing process failed, before the recall, did their Quality Systems perform their intended function?, i.e., detect the failures and prevent them from getting to the market place. A safety program or quality assurance program can be perfect on paper and defective in performance. The best Quality System in the world is worthless if the company does not implement, perform and enforce those systems. The priority placed by management on the integrity of the Quality Systems is a key component. (Pl. Ex. 500, Bliesner Report; Pl. Ex. 620, Bliesner Declaration) If upper management doesn't care about quality, the workforce charged with implementing the Quality Systems has little motivation to adhere to those programs. The test of any Quality System is in its performance. *Id.* If a company has a poor track record of putting adulterated or defective product into the market place, this is an indication or evidence of a failure in the Quality System. *Id.* If a company has a poor track record of adhering to GMPs, this is an indication or evidence of a failure in the Quality System. *Id.* If a company has internal documents that undermine the importance of its Quality System, this is also evidence of a failure. *Id.* If a company has a track

record of chronic failure in its Quality Systems, this substantially increases the probability that when defective products are produced, they will go undetected and reach the market place. *Id.* This is the type of analysis that Dr. Bliesner did in this case. *Id.* He reviewed the performance of the Quality Systems of the Defendant. *Id.* He did this by looking at the most telling evidence of whether or not this last line of defense was solid or porous. He looked at evidence that told the story of how the Quality Systems have worked in the past. *Id.*

Defendants would like to limit this inquiry to just mistakes they made in the manufacture of Digitek. This would be an artificial and misleading limitation on this sort of inquiry and intellectually dishonest. Such a limitation would make any examination of a company's ability to adhere to its Quality Systems logically flawed. Quality Systems apply to all products. *Id.* There is not one Quality System for Digitek and another for other individual products manufactured by the Defendant. Any instance of a breakdown in the Quality System at a company, no matter what the product or where in the manufacturing process it occurs, is indicative of the integrity of the whole system. Any system in a company has a failure rate. Nothing is perfect and no company Quality System performs perfectly. However, there comes a point that a company's track record of repeated failures in the performance of a Quality System passes the threshold from less than perfect to failure. *Id.* Dr. Bliesner has the expertise to make that call. *Id.* He has worked in the industry for many years. *Id.* He has done this type of review for his clients. *Id.* He has participated in the Quality Systems of companies as a chemist. *Id.* Further, Dr. Bliesner has the necessary information to make this call in this case. He has reviewed extensive documents and instances as set out in his report of repeated Quality Systems failures in Defendants' facilities. *Id.* At some point in time, more evidence of failure is just cumulative in terms of expressing a competent opinion about whether or not the Quality Systems of a company has

experienced a melt down and is ineffective. Dr. Bliesner has the expertise to know when that threshold has been reached and he has expressed the opinion that he has seen more than enough evidence to support his opinion that the Defendants had suffered a long term, chronic, substantial and sometimes, total failure of their Quality Systems. *Id.*

The inferential leap, that a failure of the last line of defense in protecting the consuming public from the Defendants' defective products probably did result in defective Digitek reaching the market, is not long. The critical importance of supported, comprehensive and fully operational Quality Systems is carefully explained in both Dr. Bliesner's report and his declaration. (Pl. Exs. 500, 620, Bliesner Report and Declaration Pl. Ex. 620). When this safeguard is impaired or is failing on a regular basis, the likelihood of defective product slipping through the cracks in the failed system is substantially increased. *Id.* The greater the dysfunction of the Quality Systems, the greater the probability that defective product will slip through and be packed. *Id.* Dr. Bliesner's opinion, based on his extensive review of the Defendants' track record, is that this company had virtually no safety net, no barriers, no reliable redundancy, and therefore little or no chance to detect and prevent the release to the consuming public of the defective Digitek that they made. In fact, any argument that they performed differently than their track record reflects, is less than plausible.

2. Plaintiffs' Experts Farley, Kenny and Somma

Plaintiffs' experts Farley, Kenny and Somma have performed essentially the same analysis as Dr. Bliesner. They looked at the same documents and have been criticized by the Defendants in the same manner as Dr. Bliesner. The Defendants set up the straw man argument and then attack the straw man. The Defendants never directly deal with the meat of all these experts' opinions in their motion to strike. They are all qualified professionals with extensive

experience in the pharmaceutical industry. They know how to call a ball and strike when it comes to evaluating whether or not a company has adequate systems in place to prevent defective product from reaching the hospitals, pharmacies and homes of patients who need this medicine. They all understand that out of specification, Digitek that is double thick and double strength, poses as serious risk to the patients who take this medicine. The Defendants know this too. They all have weighed this risk against the paltry efforts by the Defendants to do what a reasonable manufacturer would do to set up quality assurance systems so that if and when something goes wrong, the proper procedures are in place and followed to prevent defective product from reaching the market place. They have all reached the same conclusion; because the Defendants' quality systems were in such disarray, it is more likely than not that defective Digitek reached the market place. Actavis was just not capable enough to have caught all the bad tablets. (Pl. Exs. 514, 511, 516, Reports of Farley, Kenny and Somma)

III. Objection to Defendants Motion to Strike and Brief in Support.

This Court's local rules limit motions of the type filed by the Defendants in this case to 20 pages. Defendants did not seek leave of Court to exceed this limit. Plaintiffs move to strike the motions in their entirety or in the alternative, strike all pages in excess of 20 pages.

IV. Conclusion

The Defendants' arguments simply miss the point. They argue that Plaintiffs' experts should have reviewed documents that are not relevant to the opinions they express. They argue that Plaintiffs should have performed a different type of analysis, unrelated to the core questions in this case, and since they didn't, their opinions are not valid. Most telling is the fact that the Defendants do not directly attack the meat of the Plaintiffs' experts' opinions. They do not attack, because it is undeniable. This Defendant had a long and chronic history of poor quality

assurance systems performance that serves as the basis for these experts' opinions. Nor do they attack the inescapable logic that a company with an extremely poor performance record of quality assurance probably did not have the capacity to detect all the defective Digitek they made and prevent exposure to the consuming public. The Defendants' motion should be denied in all things and this case set for trial.

Respectfully Submitted:

Dated: August 24, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2011, a copy of the Response to Defendants' Motion to Exclude Plaintiffs' General Liability Experts was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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